

Europäisches Patentamt

European Patent Office

Office européen des brevets



(11) EP 1 036 567 A2

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:  
20.09.2000 Bulletin 2000/38

(51) Int. Cl.<sup>7</sup>: A61M 1/36

(21) Application number: 00103262.2

(22) Date of filing: 17.02.2000

(84) Designated Contracting States:  
AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU  
MC NL PT SE  
Designated Extension States:  
AL LT LV MK RO SI

(30) Priority: 17.02.1999 US 251619

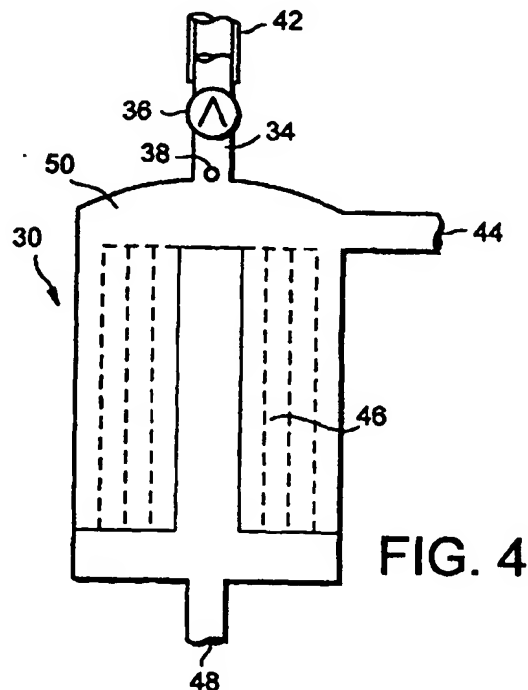
(71) Applicant: MEDTRONIC, INC.  
Minneapolis, Minnesota 55432-3576 (US)

(72) Inventors:  
• Gremel, Robert F.  
Huntington Beach, California 92649 (US)  
• Elgas, Roger J.  
Ahaheim Hills, California 92802 (US)

(74) Representative:  
Hughes, Andrea Michelle  
Frank B. Dehn & Co.,  
European Patent Attorneys,  
179 Queen Victoria Street  
London EC4V 4EL (GB)

(54) Venous filter for assisted venous return

(57) The need for a venous reservoir in a heart-lung machine is obviated by using a vacuum-purged negative-pressure air filter in the venous return line ahead of the main blood pump. The purging vacuum for the venous air filter can also be used to purge air from the cardiomy reservoir if a backflow-preventing valve is used on the venous air filter.



EP 1 036 567 A2

## Description

[0001] This invention relates to blood filters used in cardiopulmonary bypass circuits, and more particularly to a negative pressure blood filter for use in the venous line whether using assisted venous return techniques or not.

[0002] Conventional cardiopulmonary bypass uses an extracorporeal blood circuit which includes a venous drainage line, venous reservoir, blood pump, oxygenator, and arterial filter. Blood circulation is accomplished by draining blood from the patient by gravity through the venous drainage line to the venous reservoir. From there, blood drains down to the blood pump, placing this portion of the circuit at a negative pressure with respect to atmosphere. The pump supplies positive pressure to return the blood to the patient through the oxygenator and filter. The venous reservoir holds blood volume as required, while both the venous reservoir and arterial filter remove air bubbles from the blood. These may cause health problems if returned to the patient in the arterial blood flow. Air can enter the circuit from a number of sources, including around the venous cannula and through various unanticipated intra-operative events. A further complication arises if a centrifugal pump is used, in which case a large volume of air will de-prime the pump, depriving it of its pumping capability.

[0003] In order to remove air from an extracorporeal circuit prior to its use, the circuit is primed with an appropriate solution. During surgery, this solution dilutes the patient's blood, and it is therefore desirable to minimize the volume required. The venous reservoir contains a relatively large volume of fluid, and recently it has been proposed to eliminate this component of the circuit. Several problems arise, however. Without the venous reservoir between the patient and the oxygenator, any air in the venous line will either accumulate in the centrifugal pump (if used) or be pumped into the oxygenator. Furthermore, if a large bolus of air is introduced, it may de-prime the pump and oxygenator. Although arterial filters are designed to capture air bubbles, they are not designed to handle larger volumes of air such as may occur from the causes described above. Also, arterial filters are located downstream of both the pump and the oxygenator, and therefore cannot prevent air problems that would occur in those devices. Furthermore, conventional arterial filters are designed to operate at positive blood pressures.

[0004] The present invention improves upon the design of an arterial filter to allow it to be used as a venous filter at a negative pressure and to capture larger volumes of air, and, according to one aspect, provides a heart-lung machine, comprising:

- a) a venous return line receiving venous blood from a patient;
- b) an arterial supply line supplying arterial blood to

said patient;

c) a negative pressure air filter connected to said venous return line so as to cause said patient's blood to flow through said filter;

d) a blood pump and a blood oxygenator connected between said air filter and said arterial supply line, said blood pump being arranged to pump blood from said air filter toward said arterial supply line; and

e) said air filter including:

- i) a bubble trap arranged to trap air bubbles present in said patient's blood;
- ii) an air chamber arranged to receive said trapped air bubbles;
- iii) an air sensor arranged to sense the presence of air in said air chamber; and
- iv) a vacuum applied to said air chamber, said vacuum being applied when, and only when, said sensor senses the presence of air in said chamber.

[0005] According to a second aspect, there is provided a negative pressure venous air filter, comprising:

- a) an airtight container;
- b) a blood inlet on said container adapted to be connected to a venous return line for introducing venous blood into said container;
- c) a blood outlet on said container adapted to be connected to a source of negative pressure for pumping blood out of said container;
- d) an air chamber in said container;
- e) a bubble trap in said container for entrapping air in said blood and conveying it to said air chamber; and
- f) a vacuum connection at said air chamber adapted to connect said air chamber to a vacuum source for evacuating said air chamber;
- g) the suction created by said vacuum being greater than said negative pressure.

[0006] Preferred embodiments of the invention will now be described, by way of example only, with reference to the accompanying drawings.

Fig. 1 is a schematic diagram of a conventional heart-lung machine;

Fig. 2 is a schematic diagram of an AVR type heart-lung machine;

Fig. 3 is a schematic diagram of a heart-lung machine in accordance with the invention; and

Fig. 4 is a partly schematic vertical section of a filter in accordance with the invention.

[0007] Conventional heart-lung equipment, as schematically depicted in Fig. 1, draws the blood of a patient during cardiovascular surgery through a

venous line 12, oxygenates it, and returns the oxygenated blood to the patient 10 through an arterial line 14. Cardiectomy blood and surgical field debris are aspirated by a suction device 16 and are pumped by pump 18 into a cardiectomy filter 20.

**[0008]** In a conventional extracorporeal blood circuit, venous blood from line 12, as well as defoamed and filtered cardiectomy blood from filter 20, are discharged into a venous reservoir 22. In the reservoir 22, air entrapped in the venous blood (as, for example, air drawn into the blood circuit through the sutures, not shown, that attach the venous line 12 to a vein of the patient 10) rises to the surface of the blood in the reservoir 22 and is vented to atmosphere through a purge line 24. The purge line 24 is typically about a 6 mm inside diameter line, and the air space above the blood in reservoir 22 is substantial.

**[0009]** In the conventional circuit of Fig. 1, a pump 26 draws blood from the reservoir 22 and pumps it through an oxygenator 28 and an arterial filter 30 into the arterial line 14. The arterial filter is basically a bubble trap that traps any microair bubbles larger than about 20-40  $\mu\text{m}$  and discharges them to atmosphere through a typically about 1.5 mm ID purge line 32.

**[0010]** As shown in Fig. 2, it has recently been proposed to produce an assisted venous return (AVR) and to eliminate the reservoir 22, which accounts for a major portion of the priming volume of the extracorporeal blood circuit, by moving the arterial filter 30 into the venous line 12, upstream of the pump 26.

**[0011]** The filter 30 does not have an air space between its inlet and outlet, as the venous reservoir 22 does. Consequently, the negative pressure caused on the outlet side of filter 30 in Fig. 2 by the pump 26 is transmitted as suction to the venous line 12, thereby assisting the venous return from the patient 10.

**[0012]** In accordance with the invention (Fig. 3 and 4), a filter 30 of the type and size conventionally used as an arterial filter is adapted for efficient use as an AVR filter by several modifications. First, evacuation of air is facilitated by increasing the size of the purge port 34 to accept, e.g., a 6 mm ID purge line. Secondly, a vacuum greater than that normally used for venous drainage is applied to the purge port 34 to actively purge air from the filter 30. Thirdly, a check valve 36 is incorporated into the purge port to prevent air or blood from the cardiectomy filter 20 (which is at ambient pressure but is conveniently purged by the same vacuum that purges filter 30) from being drawn into the filter 30 by the negative pressure in filter 30, when the purging vacuum is not active. Fourthly, an air sensor 38 is provided in the filter 30 and is connected to activate the purge vacuum when, and only when, air is present in the filter 30. This prevents blood from being aspirated by the purging vacuum.

**[0013]** The purging vacuum may be produced by a pump 40, or it may be produced by connecting the purge line 42 to the vacuum outlet conventionally pro-

vided in operating rooms.

**[0014]** Fig. 4 shows in somewhat schematic form the filter 30 of this invention. Blood enters the filter 30 through an inlet 44 and is drawn through the filter element 46 and into the outlet 48 by the action of pump 26. A screen (not shown) or other conventional bubble-trapping device traps any air bubbles in the blood stream and causes them to rise to the top 50 of filter 30. Normally, the filter 30 is filled with blood. When air begins to accumulate at the top of filter 30, this fact is sensed by the air sensor 38. The sensor 38 activates the vacuum in the purge line 22. The vacuum at the purge port 34 overcomes the negative pressure in the filter 30 and draws out any accumulated air, shutting off under the control of sensor 38 when all the air has been removed.

## Claims

### 1. A heart-lung machine, comprising:

- a) a venous return line (12) receiving venous blood from a patient (10);
- b) an arterial supply line (14) supplying arterial blood to said patient;
- c) a negative pressure air filter (30) connected to said venous return line (12) so as to cause said patient's blood to flow through said filter;
- d) a blood pump (26) and a blood oxygenator (28) connected between said air filter (30) and said arterial supply line (14), said blood pump being arranged to pump blood from said air filter toward said arterial supply line; and
- e) said air filter (30) including:

- i) a bubble trap arranged to trap air bubbles present in said patient's blood;
- ii) an air chamber arranged to receive said trapped air bubbles;
- iii) an air sensor (38) arranged to sense the presence of air in said air chamber; and
- iv) a vacuum (34) applied to said air chamber, said vacuum being applied when, and only when, said sensor senses the presence of air in said chamber.

### 2. The heart-lung machine of claim 1, further comprising:

- f) a suction pump (16) arranged to draw cardiectomy blood from said patient;
- g) a cardiectomy filter (20) arranged to receive said cardiectomy blood, filter particulates and air therefrom, and convey filtered blood to said blood pump, said cardiectomy filter having an air chamber to receive the air filtered from said cardiectomy blood;
- h) a vacuum source (40) connected to said air chamber of said cardiectomy reservoir (20).

3. The heart-lung machine of claim 2, in which said vacuum source provides a vacuum to both said cardiomy reservoir (30) and said negative-pressure air filter (30), and in which a check valve is further so connected to said negative pressure filter to prevent the negative pressure in said negative pressure filter from drawing cardiomy blood into said negative pressure filter when said vacuum is turned off. 5
4. A negative pressure venous air filter, comprising: 10
- a) an airtight container;
  - b) a blood inlet on said container adapted to be connected to a venous return line for introducing venous blood into said container; 15
  - c) a blood outlet on said container adapted to be connected to a source of negative pressure for pumping blood out of said container;
  - d) an air chamber in said container; 20
  - e) a bubble trap in said container for entrapping air in said blood and conveying it to said air chamber; and
  - f) a vacuum connection at said air chamber adapted to connect said air chamber to a vacuum source for evacuating said air chamber; 25
  - g) the suction created by said vacuum being greater than said negative pressure.
5. The air filter of claim 4, in which said connection connecting said air chamber to said vacuum source is a purge line (34) of substantially 6mm inner diameter. 30
6. The air filter of claim 5, further comprising a check valve (36) in said purge line (34) for preventing fluid flow from said purge line into said air chamber. 35
7. The air filter of claim 4, 5 or 6, further comprising: 40
- h) an air sensor (38) arranged to sense the pressure of air in said chamber, and to activate said vacuum source when and only when air is present in said chamber. 45
- 50
- 55

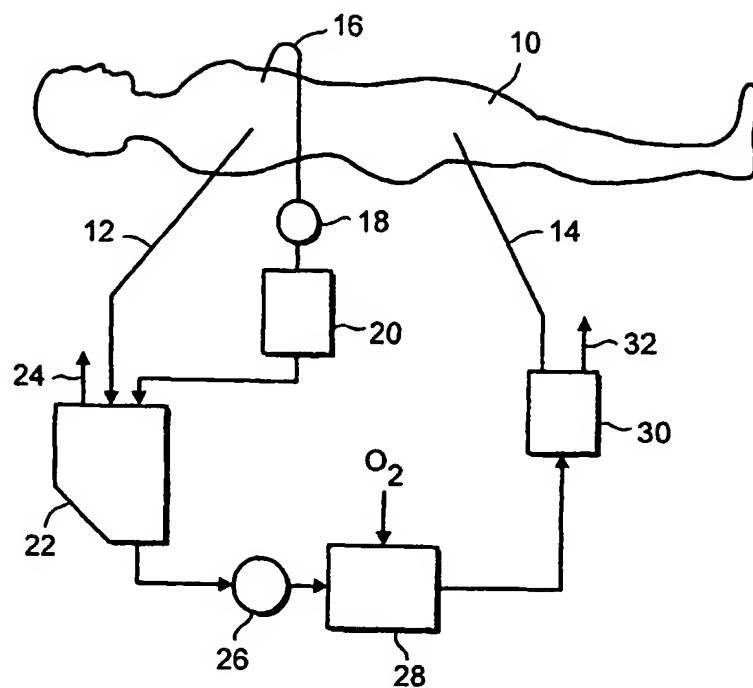


FIG. 1  
PRIOR ART

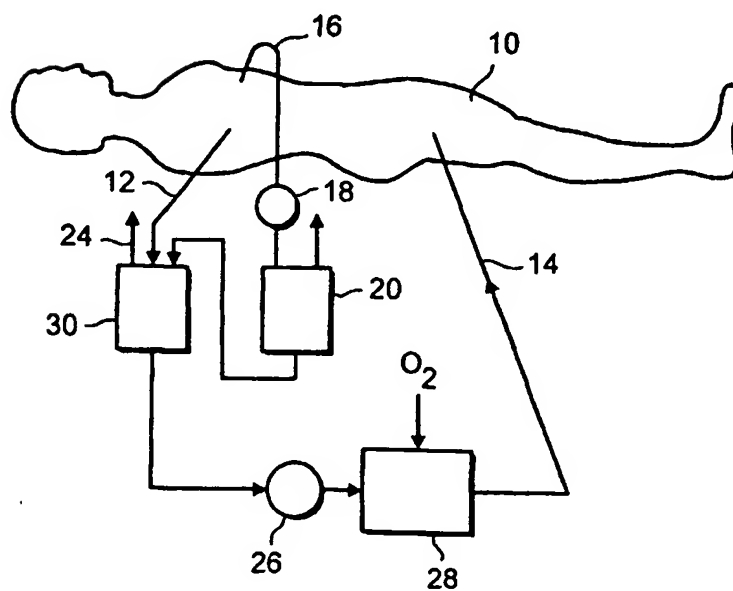


FIG. 2

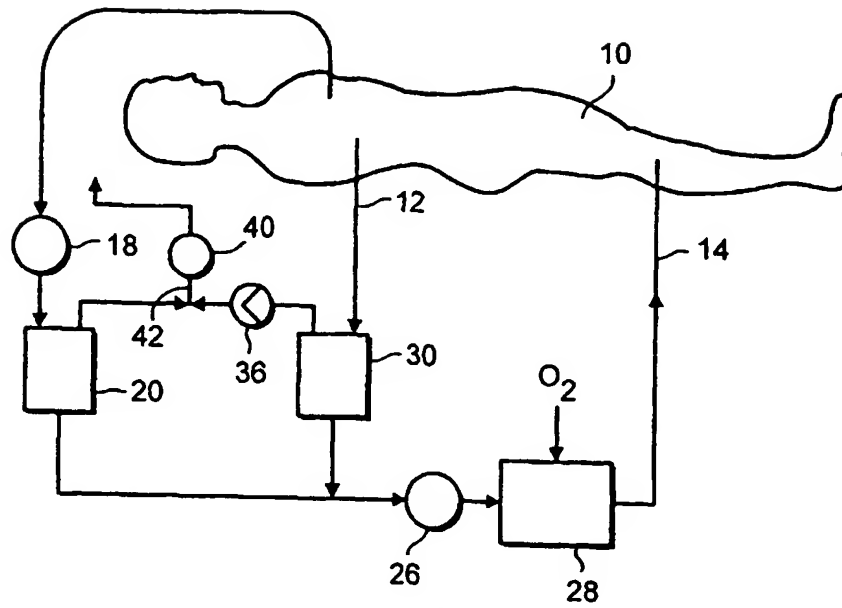


FIG. 3

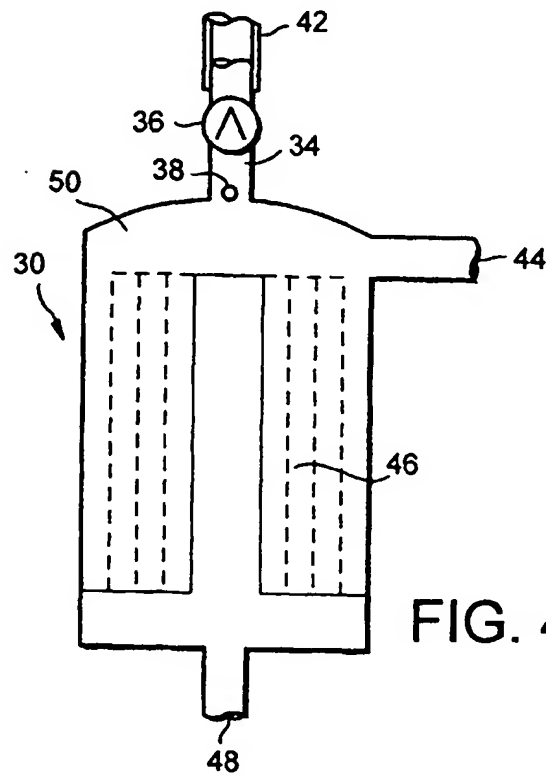


FIG. 4

BEST AVAILABLE COPY